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2000 Hollister Drive
Libertyville, Illinois 60048-3781
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MAR 5 2002

Hollister

Hollister Incorporated
InCare Pressure Biofeedback Vaginal and Anal Pressure Probes

510(k) Summary

1. Sponsor's name, Address and Contact Person

Sponsor
Hollister Incorporated
2000 Hollister Drive
Libertyville, IL
60048

Contact Person
Cindy Roberts
Hollister Incorporated
2000 Hollister Drive
Libertyville, IL 60048
Ph: (847)918-3497
Fax: (847)918-3860

Date Summary Prepared – November 5, 2001

2. Name of Device:

InCare Pressure Biofeedback Vaginal Pressure Probe
InCare Pressure Biofeedback Anal Pressure Probe

3. Name of Predicate Device(s)

InCare Pressure Biofeedback Vaginal Pressure Probe – 510(k) #K891774
InCare Pressure Biofeedback Anal Pressure Probe – 510(k) #K891774

4. Description of Device

The InCare Pressure Biofeedback Vaginal Pressure Probe and Anal Pressure Probe are designed with a silicone bladder or sack that covers the probe body and tubing that connects the probe to a pressure transducer. Once the probe is inserted into the anus or vagina the bladder is filled with air. The probes measure the strength of the pelvic floor muscles by offering resistance to a patient's voluntary contractions of these muscles.

5. Statement of Intended Use

The InCare Biofeedback Vaginal Pressure Probe and Anal Pressure Probe are intended to provide pressure biofeedback from pelvic musculature for the purpose of rehabilitation of weak pelvic floor muscles in the treatment of urinary incontinence.

6. Statement of Technological Characteristics of the Device

The InCare Biofeedback Vaginal Pressure Probe and Anal Pressure Probe are used as an accessory with the InCare Pelvic Floor Therapy devices to provide pressure biofeedback from pelvic floor musculature for the purpose of rehabilitation of weak pelvic floor muscles in the treatment of urinary incontinence. To meet the changing needs of

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Hollister Incorporated
InCare Pressure Biofeedback Vaginal and Anal Pressure Probes

Hollister's customers the InCare Biofeedback Vaginal Pressure Probe and Anal Pressure Probe has been constructed with a silicone bladder.

The InCare Pressure Biofeedback Vaginal Pressure Probe and Anal Pressure Probe (with silicone bladder) and the InCare Pressure Biofeedback Vaginal Pressure Probe and Anal Pressure Probe (K891774 – 8/23/89) are equivalent in intended use, manufacturing processes and labeling as a biofeedback therapy device for the treatment of urinary incontinence. Furthermore, product performance test results demonstrate the InCare Pressure Biofeedback Vaginal Pressure Probe and Anal Pressure Probe (with silicone bladder) and the InCare Pressure Biofeedback Vaginal Pressure Probe and Anal Pressure Probe (K891774) are equivalent in product performance.

Biocompatibility assessment of the silicone bladder has been conducted based on the principles and guidelines established by various governmental regulatory agencies and standard setting organizations. Among these are the following: United States Pharmacopoeia, General program memorandum #G95-1, United States Food and Drug Administration Office of Device Evaluation and The International Standards Organization ISO 10993-1 Biological Evaluation of Medical Devices. Based upon the results of this assessment, the silicone bladder material is considered biocompatible and appropriate for its intended use.

7. Conclusion

Based on information presented above and in the body of this premarket notification the InCare Pressure Biofeedback Vaginal Pressure Probe and Anal Pressure Probe with silicone bladder are substantially equivalent to devices currently in commercial distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 5 2002

Ms. Cindy Roberts
Global Regulatory Affairs Analyst
Hollister Incorporated
2000 Hollister Drive
LIBERTYVILLE IL 60048-3781

Re: K013653
Trade/Device Name: InCare Pressure Biofeedback Vaginal Pressure Probe and Anal Pressure Probe Non-Latex probe bladder
Regulation Number: 21 CFR 884.1425
Regulation Name: Perineometer
Regulatory Class: II
Product Code: 85 HIR
Dated: February 14, 2002
Received: February 19, 2002

Dear Ms. Roberts:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

b. Statement of Intended Use

510(k) Number (if Known): K013653
Device Name: InCare Pressure Biofeedback Vaginal and Anal Pressure Probes

Intended Use:
The InCare Biofeedback Vaginal Pressure Probes and Anal Pressure Probes are intended to provide pressure biofeedback from pelvic musculature for the purpose of rehabilitation of weak pelvic floor muscles in the treatment of urinary incontinence.

David A. Segura
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013653

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter-Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)